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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,059	02/20/2002	Steven M. Ruben	PF466P2	6326

22195 7590 08/26/2003

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/078,059	RUBEN ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant is advised that claim 21 is drawn to a gene corresponding to the cDNA sequence of SEQ ID NO: 2, but SEQ ID NO: 2 is a protein sequence.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15 and 21, drawn to polynucleotides, vectors, host cells and a recombinant method of making a polypeptide, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

II. Claims 11, 12, 16 and 24, drawn to polypeptides, classified in class 530, subclass 350.

III. Claim 13, drawn to an antibody, classified in class 530, subclass 388.22, for example.

IV. Claim 17, drawn to a method of treatment comprising administering the polypeptide of Group II, classified in class 514, subclass 12.

V. Claim 18, drawn to a method of diagnosing a pathological condition by determining the absence or presence of a mutation in a polynucleotide, classified in class 435, subclass 6, for example.

VI. Claims 19 and 20, drawn to a method of diagnosing a pathological condition by determining the presence or amount of the polypeptide of Group II and method of identifying a binding partner to the polypeptide of Group II, both by binding assays, classified in class 435, subclass 7.1, for example.

VII. Claim 22, drawn to a method of identifying an unspecified activity in a biological assay comprising expressing SEQ ID NO: 1 in a cell, isolating the supernatant, detecting an activity in a biological assay and identifying the protein in the supernatant having the activity, class and subclass undeterminable.

VIII. Claim 23, the product (protein) produced (identified) by the method of Group VII, class 530, subclass 351, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to each of inventions V and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in the method of diagnosis of invention V or in the method of identifying an activity in a biological assay from a supernatant from a cell transformed with the nucleic acid of SEQ ID NO: 1, both of which are materially different methods.

Invention I and each of inventions II, III, IV, VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides, polypeptides, antibodies and protein product of inventions I, II, III and VIII are physically and functionally distinct chemical entities that have different structures, activities and functions, and the methods of inventions IV and VI do not use the polynucleotides of invention I.

Invention II is related to each of inventions IV and VI as product and process of use. In the instant case the polypeptides can be used in the method of treatment of invention IV, but the polypeptides can also be used in a method for identifying a binding partner for the polypeptide of Group II that is invention VI, both of which are materially different methods.

Invention II is unrelated to each of inventions III, V, and VII-VIII. In the instant case the polypeptides, antibody of Group III and protein of Group VIII are physically and functionally distinct chemical entities that have different structures, activities and functions, and the polypeptides are not used in the methods of diagnosing a pathological condition by determining the absence or presence of a mutation in a polynucleotide of invention V, or in a method of identifying an activity in a biological assay of invention VII.

Invention III is related to invention VI as product and process of use. In the instant Case the antibody can be used in the method of determining the presence of amount the polypeptide of Group II, but the antibody can also be used in a method of treatment, which is a materially different method.

Invention III is unrelated to each of inventions IV, V, VII and VIII. In the instant case the antibody of Group III and protein of Group VIII are physically and functionally distinct chemical entities that have different structures, activities and functions, and the antibody is not used in the methods of treatment with the polypeptide of invention IV, or in a method of diagnosing a pathological condition by determining the absence or presence of a mutation in a polynucleotide of invention V, or in a method of identifying an activity in a biological assay of invention VII.

Invention VIII is related to invention VII in that the protein of invention VIII is

identified by the method of invention VII,

Inventions VII and VIII may be considered to be related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be manufactured by another method such as by chemical synthesis.

Invention VIII is unrelated to each of inventions IV-VI. The product of invention VIII is not used in the methods of treatment with the polypeptide of Group II, or in the method of diagnosing a pathological condition by determining the absence or presence of a mutation in a polynucleotide of invention V, or used in a method for identifying a binding partner for the polypeptide of Group II that is invention VI.

Inventions IV, V, VI and VII are unrelated to each other. The methods of the different inventions require different starting materials, and have different methods steps and goals, and are thus patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Janet Martineau on August 25, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Eileen B. O'Hara

Patent Examiner